ELECTRONIC FILING

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL UNDER 35 U.S.C. § 134(a) AND 37 C.F.R § 41.31(a)
FROM FINAL REJECTION OF CLAIMS IN:

Application of:	Pettis *et al.*	Confirmation No.:	7814
Serial No.:	09/606,909	Art Unit:	3767
Filed:	June 29, 2000	Examiner:	Witczak, Catherine
For:	INTRADERMAL DELIVERY OF SUBSTANCES	Attorney Docket No.:	11219-008-999 (P-4901)

APPELLANT'S REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41
APPEAL NO.: TO BE ASSIGNED

MAIL STOP APPEAL BRIEF – PATENTS
Commissioner for Patents
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This Reply Brief is accompanied by a Request for Oral Hearing and the associated fee required by 37 C.F.R. § 41.20(b)(3).

Payment of the required fees, and any other fees that may be due are authorized to be charged to Jones Day Deposit Account No. 50-3013.

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REPLY BRIEF

This is a Reply under 37 C.F.R. § 41.41 to the Examiner's Answer dated November 20, 2009 ("Answer") in the Appeal from the final rejection of claims 2-4, 10-13, 15, 16, and 29 in connection with the above-captioned application U.S. Serial No. 09/606,909. (Final Office Action dated September 23, 2008, "Final Action").

This Reply Brief addresses the issues elaborated in the Examiner's "Response to Argument" in Section 10 of the Answer (Ans. 7-11).[1] The remaining issues set out in the "Grounds of Rejection" in Section 9 of the Answer (Ans. 4-7) were addressed in Appellant's Brief ("Brief") filed July 31, 2009 (Br. 9-20).[2] In order not to burden the record, Appellant's positions set out in the Brief will not be repeated, but may be summarized or referenced herein.

[1] Citations to pages of the Answer and to the Final Action are indicated as "Ans.__", and "FA.__", respectively.

[2] Citations to pages of the Brief are indicated as "Br.__".

I. STATUS OF CLAIMS

Claims 2-4, 10-13, 15, 16, and 29 are rejected.

Claims 1, 5-9, 14, 25-28, and 30-31 have been canceled without prejudice or disclaimer.

Claims 17-24 and 32-39 are withdrawn.

Claims 2-4, 10-13, 15, 16, and 29 are appealed; and are the subject of this appeal.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection, set forth in the Final Office Action, are presented for review:

(1) Whether claims 2-4, 10-13, 15, 16, and 29 are properly rejected under 35 U.S.C. § 103(a) as obvious over:

(a) U.S. Patent No. 5,848,991 to Gross *et al*. ("Gross I") or U.S. Patent No. 5,807,375 to Gross *et al*. ("Gross II") which, as admitted by the Examiner, lack at least two elements of the appealed claims – *i.e.*, the depth/exposed height of the needle outlet contained within the intradermal compartment, and the specified pharmacokinetic ("PK") profile;

in view of:

(b) the teachings of the following secondary references that do *not* supply the claim elements missing from the primary Gross I and Gross II references:

(i) *transdermal devices that are designed to penetrate the epidermis – not the dermis:* U.S. Patent No. 6,611,707 to Prausnitz ("Prausnitz");

(ii) *vaccines that are not distributed systemically in the bloodstream, and therefore, do not have PK profiles*: Puri *et al.,* 2000, *Vaccine* 18: 2600-12 ("Puri"); U.S. Patent No. 6,056,716 to D'Antonio *et al.* ("D'Antonio"); and U.S. Patent No. 6,007,821 to Srivastava *et al.* ("Srivastava"); and

(iii) *drug delivery techniques yielding PKs that differ from the PK profile claimed* Autret *et al*., 1991, *Therapie* 46: 5-8 ("Autret"), and The Merck Manual of Diagnosis and Therapy (17^{th} ed.) (1999) ("the Merck Manual").

(2) Whether claims 2-4, 10-13, 15, 16, and 29 are properly rejected on the ground of nonstatutory obviousness-type double patenting over:

(a) claims 31, 32, 36, 37, 39, 49, 67, and 73 of copending Application No. 10/028,988; and

(b) claims 69, 72, 83-86, 88, 90, 100, and 103 of copending Application No. 10/028,989

in view of Gross I or Gross II, and Prausnitz, Autret, Puri, D'Antonio, and Srivastava.

III. ARGUMENT

A. SUMMARY OF ARGUMENT

The sole ground of rejection in this appeal is obviousness under 35 U.S.C. § 103(a).[3] The combination of prior art relied on lacks at least two key features of the appealed claims – the exposed height of the needle outlet contained within the targeted intradermal compartment and the pharmacokinetic (PK) profile claimed. (Br. 9-13). The Examiner's attempt to read the Appellant's teachings into the prior art to reconstruct the invention is erroneous and rejections based on these references should be reversed. (Br. 13-21). *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). (*See*, Br. 14).

Because each and every claim limitation is not found in the combination of prior art relied on, as a matter of law, the grounds alleged by the Examiner do not support a finding of obviousness. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008) (affirming the requirement that each and every claim limitation be found present in the combination of the prior art references before proceeding with an obviousness analysis).

Here, the primary Gross references are *silent* with respect to the two key features of the appealed claims. The Examiner has *not* shown these features to be *necessarily* present in Gross or *supplied* by the secondary references. A reference relied on to prove unpatentability must be so clear and explicit that those skilled in the art would have no difficulty ascertaining its meaning. *Ex parte Ouellette*, Appeal No. 2007-0807, 2008 WL 1924472, at *3 (B.P.A.I. May 1, 2008) (citing *In re Turlay*, 304 F.2d 893, 899 (C.C.P.A. 1962)). As evidenced by the opposing viewpoints reflected in the Brief and the Answer, the "teachings" of the primary Gross

[3] As indicated in the Answer, the rejections for double patenting were withdrawn as moot in view of the abandonment of the underlying applications, with the exception of 10/028,988 and 10/028,989. (Ans. 2). These outstanding double-patenting rejections should likewise be withdrawn in view of the abandonment and withdrawal of these two remaining applications.

references are, at best, ambiguous. Such ambiguity of a primary prior art reference has been held to compel reversal of obviousness rejections. *See, e.g., id. at *4* (finding ambiguity in primary reference necessitated reversal of obviousness rejection); *Ex parte Stebnicki*, Appeal No. 2006-2990, 2007 WL 1242177, at *4 (B.P.A.I. Apr. 27, 2007) (reversing claim rejections under 35 U.S.C. §§ 102(b) and 103(a) based on ambiguity of primary reference); *Ex parte Pratt,* Appeal No. 1999-0616, 1999 WL 33231759, at *3-4 (B.P.A.I. Jan. 1, 1999) (reversing claim rejections under 35 U.S.C. § 103 based on ambiguity in primary reference); and *Ex parte Sandstrom*, Appeal No. 2009-011892, 2009 WL 2625811, at *7 (B.P.A.I. Aug. 26, 2009).

Finally, assuming *arguendo* that a *prima facie* case of obviousness had been made, it is rebutted by the Appellant's evidence of record of unexpected results. (Br. 21). This evidence, *in error*, was not considered in arriving at the determination of obviousness. *In re Sullivan,* 498 F.3d 1345, 1353 (Fed. Cir. 2007) (board committed error by failing to consider evidence of unexpected results submitted to rebut *prima facie* case of obviousness); *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995) (obviousness rejection reversed in view of failure to consider unexpected results); *Ex parte Naitou*, Appeal 2009-004954, 2009 WL 2055271, at *3 (B.P.A.I. July 10, 2009) (obviousness rejection reversed finding it unclear that Examiner had fully considered evidence in specification relied on to support unexpected results).

For the foregoing reasons, the rejection for obviousness is erroneous and should be reversed.

B. ARGUMENT

1. The Claimed Invention

The invention relates to the administration of insulin to a human subject through a hollow needle that penetrates the dermis of the subject's skin so that the depth and exposed height of the

needle outlet are contained within the intradermal compartment of the skin, and applying pressure effective to control the rate of delivery, so that systemic distribution of insulin having the claimed PK profile is achieved; *i.e.,* a higher maximum plasma concentration and a higher bioavailability as compared to subcutaneous delivery of insulin. The appealed claims require positioning the needle outlet within the targeted intradermal compartment so that systemic distribution of insulin having the specified PK profile is achieved. S*ee*, appealed claim 29 and Br. 10-11 citing to appropriate portions of the specification at p. 4, *l.* 29 to p. 5, *l.* 21; in particular, p. 5, *ll.* 9-14, Example 2 and Fig. 4 that support the embodiment covered by the appealed claims.

There is no merit to the Examiner's contention that the specification contradicts Appellant's position regarding criticality of the recited parameters for achieving the PK profile of the appealed claims. (Ans. 7, last ¶ bridging to 8 citing Br. at 11). The portions of the specification relied on for the "contradiction" describe injection devices in general and ranges of depths to be targeted in the skin to achieve systemic distribution of drugs with various PK profiles (*i.e.*, specification, p. 4, *ll.* 3-6 cited by Examiner at Ans. 7-8). But there is no contradiction -- the specification may describe more embodiments than what is claimed. Here, the appealed claims cover a preferred embodiment that is supported by the specification (*e.g*, at p. 4, *l.* 29 to p. 5, *l.* 21; in particular, p. 5, *ll.* 9-14, Example 2 and Fig. 4 cited at Br. 10-11). As a matter of law, an applicant is entitled to claim less than the specification discloses. *In re Saunders,* 444 F.2d 599, 607 (C.C.P.A. 1971).

2. The Combination of Prior Art References Relied on by the Examiner Does Not Support Finding Obviousness

To find obviousness, each and every claim limitation must be found in the combination of prior art relied on. *See, Abbott Labs.*, 544 F.3d at 1351, where the Federal Circuit confirmed

that *KSR Int'l Co.* does not affect the requirement that each and every claim limitation be found present in the combination of the prior art references before the analysis proceeds. In *Abbott Labs.*, the claims covered an extended release antibiotic composition and required a specified PK profile. *Id.* at 1344. The Court found that the claims were not made obvious where the PK limitations were not disclosed in the prior art and not shown to be inherent to the structural limitations of the prior art. *Id.* at 1351. As aptly put by the Federal Circuit, "[k]nowledge of the goal does not render its achievement obvious." *Id.* at 1352. The facts in the present appeal are strikingly similar and warrant the same result.

(a) The Examiner Admits That The Primary Gross References Are Silent Regarding Two Elements Of the Appealed Claims and are Insufficient to Support the Rejection for Obviousness

As admitted by the Examiner, each of the Gross references U.S. Patent No. 5,848,991 and U.S. Patent No. 5,807,375 lacks at least two elements of the appealed claims – *i.e.*, the depth/exposed height of the needle outlet contained within the intradermal compartment, and the specified PK profile. (*See*, Ans. 4, and FA. 3 where the Examiner states, "Gross '991 and Gross '375 are silent with respect to the needle outlet exposed height of 0-1 mm and the pharmacokinetic profile of the ID delivered drugs.").

None of the outstanding rejections are based on the Gross references alone. This is understandable because, as a matter of law, the Gross references alone are not sufficient to render the claims obvious since they are missing two elements of the claims. The Examiner's attempt to fill in the gap fails – the evidence in this record does not show that these features are necessarily present in Gross or supplied by the secondary references.

(b) The Examiner, In Error, Attributes Appellant's Claimed Needle Outlet Parameters To the Primary Gross References Which Lack This Feature

Admitting that Gross is silent regarding the needle outlet and its containment within the range of depths required to achieve the PK profile of the appealed claims, the Examiner then attempts to "re-engineer" Gross to arrive at the claimed invention. (Ans. 4-5 and 8-9). Here, in error, the Examiner uses the Appellant's own teaching, and Prausnitz (U.S. Patent No. 6,611,707) -- a reference relating to transdermal systems that teaches away from delivery to the dermis -- to reconstruct the invention.

Appellant challenges the Board to find disclosure in Gross of a needle outlet of about 0 to 1 mm and its placement at a depth of 0.25 to 2 mm, preferably 0.75 to 1.5 mm as alleged by the Examiner (at Ans. 4, 2nd ¶, and FA. 2-3). In fact, these measurements cannot be found anywhere in the Gross references. Nor can they be derived by combining Gross with Prausnitz's 0 mm needle outlet (as alleged by the Examiner at Ans. 4, last ¶ to 5, and 9) without using the Appellant's teachings. Instead, these parameters were taken directly from Appellant's specification (at p. 5, *ll.* 9-21, in particular, *ll.* 11-13). Here, the Examiner has run afoul of the Supreme Court's admonition in *KSR Int'l Co.* to guard against reading into the prior art the teachings of the invention in issue. 550 U.S. at 421. (Br. 13-14).

With respect to Prausnitz, the Examiner now admits, "as pointed out by Appellant, Prausnitz teaches using microneedles which target the transdermal layer (as opposed to the intradermal layer . . . ." (Ans. 9). In fact, Prausnitz teaches away from delivery to the dermis. *See,* Br. 15-16 quoting Prausnitz at col. 4, *ll.* 7-11, describing the design of transdermal devices "so that insertion of the microneedles into the skin does not penetrate into the dermis . . . ." Since Prausnitz teaches avoiding intradermal delivery, there is no discernible reason on this

record that the skilled artisan would have grafted the teachings of Prausnitz into Gross. Again, the Examiner's analysis falls prey to the insidious effects of hindsight reconstruction.

(c) The Examiner, In Error, Departs from the Art-Recognized Understanding of the Term "Bioavailability" to Arrive at the Conclusion that this Claim Feature is Supplied by the Prior Art

The appealed claims require a PK profile that exhibits both a higher maximum plasma concentration (C_{max}) and a higher bioavailability as compared to subcutaneous delivery of insulin. (Br. 10, 18-21 and claim 29). The Examiner's obviousness analysis hinges on a misinterpretation of the claim term "bioavailability." (*See* Ans. 9-10).

The specification assigns no special meaning to the term "bioavailability." The Appellant submitted evidence, including treatises and expert declarations establishing its art-recognized meaning. This evidence shows that, "bioavailability" is measured by, and essentially synonymous with "AUC" (**a**rea **u**nder the **c**urve), and that other PK parameters such as T_{max} and C_{max} can be misleading if used as indicators of bioavailability. (Br. 18-21). The Examiner, in error, rejected this evidence and substituted her own opinion. As a result, the Examiner redefined the term in a way that departs from the art-accepted meaning. According to the Examiner *any* PK parameter, including C_{max}, T_{max} or AUC is a measure of bioavailability. (Ans. 10). Using this newfound definition, the Examiner "shoehorned" PK profiles that do not exhibit an improved AUC into the scope of the claims. Thus lowering the bar, the Examiner now contends that the appealed claims are made obvious by prior art that does *not* describe, disclose or demonstrate, expressly or inherently, improved bioavailability as measured by an increased AUC. The basis for these rejections is in error. The Board should adopt the expert testimony over the Examiner's unsupported opinion to properly interpret the appealed claims and the prior art relied on. *In re Lemin,* 364 F.2d 864, 867 (C.C.P.A. 1966) (where the Court reversed the

Examiner's rejection noting, "[w]hile the examiner is presumed to be an expert in his field of examination, and while, in the absence of instruction, we might be inclined to agree with him . . . we must, in making determinations under section 103, give weight to the sworn statements of workers skilled in the art as to the meaning to them of symbols with which they, and not we, are familiar. This is particularly so when, as here, questions of convention and custom come into dispute.").

Notably the Federal Circuit and district courts have construed the claim term "bioavailability" consistently with Appellant's position – concluding it means the total exposure of drug in the bloodstream as measured by the AUC. In *Abbott Labs. v. Sandoz, Inc.*, the Federal Circuit noted, "[t]he AUC is a calculation of the 'area under the curve' when drug concentration is plotted over time, and is a measure of bioavailability of the drug. " 544 F.3d at 1353 n.3. The district court's construction of the term "bioavailability" (affirmed by the Federal Circuit) was more detailed: "the total exposure of . . . [the drug] . . . in the bloodstream as measured by the logarithm-transformed area under the plasma concentration curve ("*AUC*"), which is a mathematical and visual representation of the aggregate amount of the drug reaching systemic circulation over a given period of time." *Abbott Labs. v. Sandoz, Inc.,* 500 F. Supp.2d 807, 831 (N.D. Ill. 2007). The district court further noted that the term "bioavailability" does *not* encompass both the rate and effect of release -- which are measured using C_{max} and C_{min}. *Id.* Thus, the Examiner's construction is at odds with the ordinary meaning ascertained by the courts in *Abbott Labs. v. Sandoz, Inc.*

While the patent in suit in *Abbott Labs. v. Sandoz, Inc.* (US 6,010,718) is not related to the application in this Appeal, the courts' interpretation of the term "bioavailability" is relevant to the issues in this Appeal. The patent in *Abbott Labs. v. Sandoz, Inc.* was filed in the relevant time period (1997) and did not attribute a special definition to the term. The court assigned the

term its plain and ordinary meaning as understood by the skilled artisan at the time. In fact, the meaning of the term was not disputed by the parties. *See Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp.2d at 830-31. The Appellant's construction of the term "biocompatibility" is consistent with the Federal Circuit's, and cannot be "misleading" as contended by the Examiner. (Ans. at 9). Quite the contrary, the Examiner's construction is at odds with the plain and ordinary meaning of the claim term as it has been interpreted by the Federal courts, notably, the Federal Circuit.

The Appellant recognizes that, unlike claim construction methods used by courts for issued patents where claim language is fixed, during patent prosecution the pending claims must be interpreted as broadly as their terms *reasonably* allow. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989); *In re Okuzawa*, 537 F.2d 545, 548 (C.C.P.A. 1976). Here, however, the Examiner's interpretation of the claim term "bioavailability" is *not reasonable* – not only is it at odds with the art-accepted meaning, it is at odds with the claim language itself! The appealed claims specify *two limitations* that must be higher than that achieved by subcutaneous delivery of insulin – one limitation is the C_{max} and the other, *bioavailability*. If C_{max} were a measure of bioavailability as contended by the Examiner, these claim limitations would be redundant. Clearly, the reasonable interpretation of "bioavailability" is to adopt the art-accepted meaning of the term as synonymous with AUC. *See Ex parte Liu*, Appeal No. 2008-006337, 2009 WL 3151031, at *3 (B.P.A.I. Sept. 29, 2009); *Ex parte Richardson*, Appeal No. 2009-003991, 2009 WL 3816887, at *4 (B.P.A.I. Nov. 12, 2009); and *Ex parte Nambu*, Appeal No. 2009-009366, 2009 WL 3837049, at *2 (B.P.A.I. Nov. 13, 2009) confirming that during prosecution, claim terms are to be given their broadest *reasonable* meaning in their ordinary usage *as they would be understood by one of ordinary skill in the art*, taking into account whatever enlightenment by way of definitions or description in the applicant's specification.

When the appealed claims are properly interpreted, it is clear that the drug delivery system described by Autret yields PKs that differ from the PK profile claimed. Autret, relied on by the Examiner (Ans. 6 and 10), describes a drug delivery system for calcitonin (not insulin). Importantly, Autret expressly states that the AUC achieved is *not* different from that obtained by subcutaneous injection. Thus, Autret does not describe or achieve the PK profile claimed. (Br. 18-21).

The "vaccine art" cited by the Examiner (Puri, D'Antonio and Srivastava; Ans. 5-6 and 10) is not applicable to the insulin delivery system and PK profile claimed (Br. 15-21). These references do not describe PK profiles at all. Vaccines are not distributed systemically in the bloodstream, and therefore, do not display PK profiles. It is apparent from the vaccine references themselves that the Examiner's position (at Ans. 5-6 and 10) is incorrect. *See* Br. 16-18 and note 2 explaining that vaccines function through a local, cellular response instead of systemically.

In sum, the limitations of the appealed claim, whereby the bioavailability of the insulin delivered is characterized, are not shown as achieved in any reference or any combination of references of record in this appeal. *See*, *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d at 1348, 1351 where such a finding compelled a conclusion that obviousness had not been established.

(d) The Examiner and Appellant Disagree on Gross' Inherent Teachings: As a Matter of Law, Such Ambiguity Cannot Support Unpatentability

Contrary to the conclusion (at Ans. 11), the Examiner has not shown that the claimed PK profile is necessarily present or inherent in Gross. In fact, rejections of the claimed subject matter on the grounds of inherent anticipation by Gross were raised during prosecution and have

been resolved.[4] There is no evidence in this record that practicing Gross would necessarily result in a PK having both a higher C_{max} and bioavailability (AUC) for insulin distribution as compared to subcutaneous delivery. In fact, the Appellant presented evidence that practicing Gross does *not* necessarily result in the PK profile required by the appealed claims. (Kasting Decl., Second Pettis Decl., and Third Pettis Decl.). Moreover, the Appellant requested evidence to the contrary by way of an Examiner's affidavit pursuant to 37 C.F.R. § 1.104(d)(2) (October 7, 2005 Amendment at p. 15). The evidence requested from the PTO was not forthcoming, and the rejections were not repeated thereafter. *Ex parte Means*, Appeal No. 96-4194, 1996 WL 1771381, at *3 (B.P.A.I. 1996) ("Inasmuch as the examiner has not responded to appellants' challenge with either a reference teaching or a declaration executed by the examiner, we *must* reverse the obviousness rejection . . . .") (emphasis added).

In essence, the Examiner has one interpretation of Gross' "teachings" (Ans. 8-9) and Appellant another. (Br. 13-15). The Appellant believes that the evidence does not support the teaching in Gross alleged by the Examiner, and that the Appellant's interpretation of Gross is more plausible in view of the surrounding facts and circumstances. Should the Board be unable to decide who is right, then Gross' teachings must be found to be ambiguous, and cannot support unpatentability under 35 U.S.C. §§ 102 or 103. A reference relied on to prove unpatentability, *i.e.*, for anticipation or obviousness, must be so clear and explicit that those skilled in the art will have no difficulty in ascertaining its meaning. *Ex parte Ouellette*, Appeal No. 2007-0807, 2008 WL 1924472, at *3 (B.P.A.I. May 1, 2008) (finding that ambiguity in primary reference necessitated reversal of rejections based on anticipation and obviousness, citing *In re Turlay*,

[4] *See*, April 7, 2005 Office Action, at page 4, and Amendment filed October 7, 2005 accompanied by the Declaration of Dr. Gerald Kasting Under 37 C.F.R.§1.132 ("Kasting Decl.") and the Second Declaration of Dr. Ronald J. Pettis Under 37 C.F.R. §1.132 ("Second Pettis Decl.")), see also, Amendment filed June 18, 2007 at pp. 7-8 accompanied by Third Declaration of Dr. Ronald J. Pettis Under 37 C.F.R. §1.132 ("Third Pettis Decl.").

304 F.2d 893, 899 (C.C.P.A. 1962)); *see also Ex parte Stebnicki*, Appeal No. 2006-2990, 2007 WL 1242177, at *4 (B.P.A.I. Apr. 27, 2007) (finding that ambiguity in primary reference necessitated reversal of rejections based on anticipation and obviousness); *Ex parte Pratt,* Appeal No. 1999-0616, 1999 WL 33231759, at *3-4 (B.P.A.I. Jan. 1, 1999) (reversing claim rejections under 35 U.S.C. § 103 based on ambiguity in primary reference); and *Ex parte Sandstrom*, Appeal No. 2009-011892, 2009 WL 2625811, at *7 (B.P.A.I. Aug. 26, 2009).

3. Unexpected Results That Rebut Obviousness, In Error, Have Not Been Considered

The evidence of record shows that the claimed delivery method unexpectedly achieves a PK profile superior to subcutaneous delivery of insulin. (*See*, Br. 21, specification Ex. 2 and Fig. 4, and First Pettis Decl.). This evidence, in error, was not considered in arriving at the determination of obviousness. *In re Sullivan*, 498 F.3d 1345,1353 (Fed. Cir. 2007) (board committed error by failing to consider evidence of unexpected results submitted to rebut prima *facie case* of obviousness); *In re Soni,* 54 F.3d 746, 751 (Fed. Cir. 1995) (obviousness rejection reversed in view of failure to consider unexpected results where examiner acknowledged that prior art was *silent* as to molecular weight of polymer used, but nevertheless argued that a person of ordinary skill would have selected a polymer having a molecular weight within the claimed range); *Ex parte Naitou*, Appeal No. 2009-004954, 2009 WL 2055271, at *3 (B.P.A.I. July 10, 2009) (obviousness rejection reversed finding it unclear that Examiner had fully considered evidence in specification relied on to support unexpected results); *Ex parte Donnelly*, Appeal No. 2009-014598 (B.P.A.I. Jan. 5, 2010) (obviousness rejection reversed because Examiner failed to properly consider the evidence proffered for unexpected results); *Ex parte Pollard*, Appeal No. 2009-004349 (B.P.A.I. Jan. 7, 2010) (obviousness rejection reversed finding that the

Examiner failed to make the requisite factual findings and failed to articulate a rationale for combining the features of the applied references to support a *prima facie* case of obviousness).

4. Miscellaneous Matters

(a) Evidence Relied Upon

The diagram in Appellant's Brief (Br.11) was not submitted as evidence (see Ans. 3, last ¶) but merely as an illustration of the Appellant's point regarding the containment of the needle outlet in the targeted intradermal compartment. Appellant reserves the right to use the diagram at Oral Argument to assist the panel's understanding of Appellant's position.

(b) Evidence Appendix

Copies of the documents identified in the Evidence Appendix (Br. 31-32) were not uploaded on PAIR and are submitted electronically as a separate document for the convenience of the Board.

CONCLUSION

For the reasons given in this Reply Brief and in the Appeal Brief, reversal of all the rejections is requested.

Respectfully submitted,

Date: January 20, 2009 /Laura A. Coruzzi/ ,30,742
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